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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,230	02/04/2004	Jan Johansson	290168.121 US4	2415

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EXAMINER

WOODWARD, CHERIE MICHELLE

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/772,230	JOHANSSON, JAN	
	Examiner	Art Unit	
	Cherie M. Woodward	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 5-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/4/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Formal Matters***

1. The Preliminary Amendment filed on 4 February 2004, has been entered. Claims 5-9 are pending and under examination.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on 4 February 2004 has been considered. A signed copy is attached hereto.

### ***Specification***

3. The cross-references to related applications in the first paragraph of the specification should be updated to reflect that Application 09/988,842, filed 11/19/2001, has issued as US Patent 6,716,589. See 37 CFR 1.78 and MPEP § 201.11.
4. The specification is objected to because of alterations on page 6, which have not been initialed and/or dated as is required by 37 CFR 1.52(c). Appropriate correction is required.

### ***Drawings***

5. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figures 10 and 11 contain multiple figures. These individual figures should be labeled Figure 10A, 10B, 10C, 11A, and 11B, respectively, in both the drawing and the specification. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 5-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Soto et al., (Biochem and Biophys Res Com. 1996; 226:672-680).

The claims recite a method of identifying whether a protein is susceptible to forming amyloid, comprising analyzing the amino acid sequence of the protein to determine whether the protein contains a predicted discordant helix, wherein the presence of predicted discordant helix is an indication that the protein is susceptible to forming amyloid; wherein the discordant helix is at least six amino acids in length; a method of decreasing the rate of formation of  $\beta$ -strand structures between at least two discordant helix-containing polypeptides, comprising contacting the discordant helix-containing polypeptides with a compound that stabilizes an  $\alpha$ -helical form of the discordant helix; a method of treating an individual having or at risk for having an amyloidosis, the method comprising administering to the individual a therapeutically effective amount of a compound that stabilizes an  $\alpha$ -helical form of a discordant helix-containing polypeptide that forms amyloid; wherein the amyloidosis is selected from the group consisting of prion diseases and Alzheimer's disease.

Soto et al., teach that pH, peptide concentration, and solvents can influence the conformation of A $\beta$  peptides (p. 675, first paragraph). These factors can determine whether the A $\beta$  peptide adopts an  $\alpha$ -helix or a  $\beta$ -sheet conformation. Soto et al., teach that hydrophobicity facilitates monomeric interactions that thermodynamically drive A $\beta$  peptides to convert from  $\alpha$ -helices to  $\beta$ -sheets, which produce amyloid fibrils (p. 673, first paragraph). Soto et al., also teach the use of a structure prediction algorithm to determine the probability that residues 15-25 of A $\beta$  will form a  $\beta$ -sheet (p. 673, paragraphs 4 and 5; p. 674, Figure 1). Soto et al., teach the limitations of a "discordant helix" as defined in the instant disclosure (p. 4), as an amino acid sequence that is predicted to be able to form either an  $\alpha$ -helix or  $\beta$ -sheet (p. 674, Figure 1). Soto et al., also teach the use of an inhibitor of A $\beta$  fibrillogenesis peptide 1 (iA $\beta$ 1), an 11 amino acid peptide, to prevent the adoption of  $\beta$ -sheets in A $\beta$  so that the maintenance of  $\alpha$ -helices is favored (p. 674, second paragraph). Derivates of iA $\beta$ 1, including a shorter 7 amino acid inhibitor, designated iA $\beta$ 3, are also taught (p. 676, last paragraph to p. 677, first paragraph; and p. 678, Table 1). Soto et al., also teach a method of determining the percentage of amyloid formed per concentration of iA $\beta$ 1 (Figure 2A, 3A, 4A, and Table 1), thus showing that the smaller peptide inhibitors are able to successfully decrease the rate of formation of  $\beta$ -strand structures. Soto et al., teach that the anti- $\beta$ -sheet peptides and derivatives, including cyclic peptides or peptide mimetic molecules may be used to prevent and/or retard amyloidosis in vivo in Alzheimer's disease and other types of amyloid related disorders (p. 678, last paragraph to p. 679, first paragraph).

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*Conclusion*

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Uversky et al., (Proteins. 2000 Nov 15; 41:415-427) disclose natively unfolded proteins due to physiological conditions.

Chiti et al., (PNAS USA. 1999 Mar; 96:3590-3594) disclose conditions for in vitro formation of amyloid protofilaments and fibrils.

Lopez de la Paz, (PNAS USA. 2004 Jan 6; 101(1):87-92) disclose sequence determinants of amyloid fibril formation

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cherie M. Woodward whose telephone number is (571) 272-3329. The examiner can normally be reached on Monday - Thursday 9:00am-7:30pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CMW

AU 1647

*Marianne P. Allen*  
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PRIMARY EXAMINER  
9/26/06  
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